REMARKS

I. Introduction

Receipt is acknowledged of a non-final Office Action dated September 20, 2004. In the action claims 9-10, 60, 61 and 65 were rejected as allegedly containing new matter, claims 1-10, 12, 13, 60, 61, and 62-65 were rejected as allegedly lacking utility, claims 3, 4, 6-9, 12, 13, 62, and 64-66 as allegedly failing to meet the written description requirement, calims 3, 6-10, 12, 60, 61, and 64-66 as allegedly indefinite, and claims 3-10, 12 and 62-66 as allegedly anticipated by Caput *et al.*, PCT publication WO 92/09629 and/or Hromas *et al.*, *J. Immunol.*, 159:2554-58 (1997) ("Hromas"). Claims 9-10, 12 and 66 were also objected to for formality reasons.

II. Status of the Claims

In this response applicants canceled claims 60 and 61, and amended claims 3, 4, 9, 10, 12, 62, 65 and 66. Claims 3 and 62 were amended to claim variants sharing at least 97% sequence identity to SEQ ID No. 4; claim 9 was amended so as to not depend on a withdrawn base claim; claims 4, 10, 12 and 65 were amended for formality reasons; and claim 66 was amended to recite a structural feature (*i.e.*, SEQ ID NO: 4). Support for amended claims 3 and 62 can be implicitly found on page 6, last full paragraph. Support for amended claims 4, 10, 12 and 65 can be found in originally filed claims 4, 10, 12 and 65, and support for amended claim 9 can be found in the specification on page 6, last full paragraph. Support for claim 66 can be found throughout the specification and on page 8, first full paragraph in particular. Upon entry of this amendment, claims 3-10, 12, 13, 62-66 will be under examination.

III. Priority

Claims 3, 6, 7-10, 60, and 62-65 were rejected as allegedly not supported by the priority document. In particular, the examiner stated that since the claims "contain language that does no [*sic*] have support in the parent application, priority is not granted to the parent application for these claims" and that the at least 90% sequence identity to the amino acid

sequence of SEQ ID NO. 4 "is not supported by written description in the prior application." Office Action at 3.

Without acquiescing to the Office's rejection, applicants amended the claims to recite "at least 97% sequence identity to the amino acid sequence of SEQ ID NO: 4." This amendment is implicitly supported in the specification at 6, last full paragraph, since the specification explicitly states that the polypeptides of the present invention may comprise an insertion or deletion of 1 to 5 amino acids. Assuming applicants change 1 to 5 amino acids in SEQ ID NO: 4, the modified sequence would share approximately 97% to 100% sequence identity with SEQ ID NO: 4. Thus, this amendment is implicitly supported in the present application as well as the priority document. Accordingly, withdrawal of this ground for rejection is respectfully requested.

IV. Claim Objections

Claims 9-10 were objected to for being dependent on a non-elected base claim. Accordingly, applicants amended claim 9 so as to not depend on claim 1, and claim 10 depends from now independent claim 1, thereby rendering the instant rejection moot.

Also, claims 12 and 66 were objected to for formality reasons. The amended claims render this rejection moot.

V. New Matter Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 9-10, 60, 61 and 65 were rejected under 35 U.S.C. 112, first paragraph, as allegedly containing new matter. Specifically, claims 60 and 61 were rejected for reciting negative limitations that are allegedly not supported in the application, and claims 9, 10 and 65 were rejected because they recite "an insertion or deletion of 1-5 amino acids as compared with SEQ ID NO: 4" or a list of specific amino acid substitutions.

Without acquiescing to the examiner's rejection, and in the interest of expediting prosecution, applicants canceled claims 60 and 61.

Regarding claims 9, 10 and 65, applicants amended claim 9 so as to not recite these features. Claim 65 does not comprise new matter. In fact, as previously stated in applicants June 14, 2004 response, a polypeptide that consists essentially of an insertion or deletion of about 1 to 5 amino acids compared with SEQ ID NO. 4 can be found on page 6, last full paragraph of the specification (**which specifically provides** that "'[i]nsertions' or 'deletions' are typically in the range of about **1 to 5 amino acids**."). Applicants, however, amended claim 65 to more clearly recite the present invention.

VI. Lack of Utility Rejection Under 35 U.S.C. 101 and 35 U.S.C. 112, First Paragraph

Claims 1-10, 12, 13, 60, 61 and 62-65 were rejected under 35 U.S.C. 101 and 35 U.S.C. 112, first paragraph, because "the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Office Action at 8 and 13.

The claimed polypeptides and polynucleotides encoding them are pancreatic expressed chemokines. *See e.g.*, specification at 5, first full paragraph. This is a "specific and substantial utility" as required by the statute, and one of skill in the art would know what is meant by a chemokine and how to use such chemokines.

In addition, the post-filing date art cited by the examiner does more than suggest that PANEC-2 (SEQ ID NO: 4) is expressed in a wide variety of tissue. Nagira *et al.*, *J. Biol. Chem.* 272:19518-24 (1997) ("Nagira"), states that they have identified a novel human CC chemokine and that "[it] is specifically chemotactic for lymphocytes." Nagira at 19519, first full paragraph.

Moreover, "[w]here an applicant has specifically asserted that an invention has a particular utility, that assertion cannot simply be dismissed by Office personnel as being 'wrong,' even when there may be reason to believe that the assertion is not entirely accurate." M.P.E.P. § 2107.02. Additionally, the Office stated that "[a]n assertion is credible unless (A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion." *Id.* But as stated above, the post-filing date publication cited by the examiner (Nagira) does not indicate that

the utility asserted in the present invention is flawed. In fact, this reference further asserts the claimed utility.

Further, the Office stated that "[t]he specification does not elucidate or demonstrate any particular target for the instantly disclosed chemokine, but instead teaches that excessive expression of PANEC-2 'can' lead to activation of monocytes, macrophages, basophils, eosinophils, T-lymphocytes and/or other cells which respond to chemokines" and that "this is not a definitive assertion of functionality or utility." Office Action at 11. However, to provide a credible assertion of utility, it is not necessary to show which cells are specifically activated by the chemokine, but that the novel compounds of the present invention are, or encode chemokines. Disclosing the mechanism by which the chemokine acts is beyond the scope of demonstrating utility. Thus, in view of the foregoing, applicants respectfully request the rejection be withdrawn.

VII. Written Description Rejection Under 35 U.S.C. 112, First Paragraph

Claims 3, 4, 6-9, 12, 13, 62 and 64-66 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to meet the written description requirement. Essentially, the claims were rejected because variants, biologically active fragments, and immunogenic fragments of SEQ ID NO. 4 are allegedly not described in the instant specification. Applicants respectfully traverse this ground for rejection.

A skilled artisan, based on the teachings of the specification, polypeptide variant sharing at least 97% sequence identity to SEQ ID NO: 4 and possesses chemokine activity is adequately described. Because of the redundancy in the genetic code and the teachings in the application, a skilled artisan would know what nucleotides to change to encode a polypeptide that corresponds to the amino acid sequence of SEQ ID NO: 4. Additionally, a skilled artisan would know what amino acid substitutions could be made to SEQ ID NO: 4 so as to preserve the chemokine functionality of the protein. And since part b) of the claim recites at least 97% sequence identity to SEQ ID NO: 4, only a finite number of substitutions could be made and the activity of the polypeptide variants could be readily assessed by following the assay described in example XII. See specification at 21.

Regarding biologically active and immunogenic fragments consisting essentially of SEQ ID NO: 4, such fragments are described on page 7, first full paragraph. The claimed fragments must also have chemokine activity and the functionality of the fragment can then be determined based on known methods. Indeed, chemokines are known compounds in the art and one of skill in the art would know what how to assess whether a given protein has chemokine activity.

Claim 66 was specifically rejected for being "entirely devoid or any structural limitation as it does not provide any reference sequence against which the 'substitutions' are compared . . . ." Office Action at 18. In the interest of expediting prosecution, applicants amended claim 66 to refer to SEQ ID NO: 4. Support for this amendment can be found on page 8 of the present specification.

Therefore, for at least these reasons, applicants' claims satisfy the written description requirement of § 112, first paragraph, and withdrawal of this ground for rejection is respectfully requested.

VIII. Indefiniteness Rejection Under 35 U.S.C. § 112, second paragraph

Claims 3, 6-10, 12, 60, 61 and 64-66 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. In the interest of expediting prosecution, applicants amended claims 3, 4, 10, 12, 65 and 66 to more clearly recite the present invention. However, applicants did not amend claim 64 because contrary to the Office's assertion, claim 64 recites a reference sequence to which the substitutions are relative. In other words, claim 64 depends on claim 62 and claim 62 recites a polypeptide variant that shares at least 97% sequence identity with SEQ ID NO: 4.

IX. Lack of Novelty Rejection Under 35 U.S.C. § 102

Claims 3, 4, 6-9, 12 and 66 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Caput *et al.*, PCT Publication WO 92/09629 and claims 3-10, and 62-65 were rejected as allegedly anticipated by Hromas *et al.* (*J. Immunol.*, 159:2554-2558 (1997)). Applicants respectfully traverse this ground for rejection.

A. Caput does not anticipate the present invention

Claims 3, 4, 6-9, 12 and 66 were rejected because Caput allegedly teaches the immunogenic fragment as presently claimed. Specifically, the Office stated that Caput teaches "a polynucleotide that encodes residues 75-78 of SEQ ID NO: 4, and [that] this four amino acid fragment would be immunologically active . . . ." Office Action at 23. Without acquiescing to the rejection, applicants amended claims 3 and 9 to recite that the immunogenic fragment is at least 5 amino acids in length. Support for this amendment can be found on page 12, first full paragraph of the present specification.

Additionally, the claims were rejected because Caput "teach[es] an isolated polynucleotide encoding a polypeptide that is an allelic variant or recombinant variant of SEQ ID NO: 4[,] wherein said variant has an insertion or deletion of 1-5 amino acids compared to SEQ ID NO: 4." Office Action at 24. Applicants respectfully traverse this ground for rejection.

Caput does not teach a polynucleotide that encodes a polypeptide consisting essentially of SEQ ID NO: 4 having an insertion or deletion that consists essentially of about 1 to 5 amino acids. Indeed, the Office previously stated that the nucleic acid taught by Caput "contains a large number of additional insertions and deletions relative to SEQ ID NO: 4." February 25, 2004 Office Action at 23. Claim 9 no longer recites this feature and claim 65 recites polypeptide that consists essentially of SEQ ID NO: 4 having an insertion or deletion consisting essentially of about 1 to 5 amino acids. Thus, SEQ ID NO: 4 consists essentially of insertions or deletions of about 1 to 5 amino acids, not an unlimited number of insertions or deletions, or the number required to obtain the sequence disclosed in Caput.

As a final note, Caput also does not teach a polynucleotide of SEQ ID NO: 3, or a polynucleotide encoding a polypeptide of SEQ ID NO: 4 or a polypeptide variant that shares at least 97% sequence identity with SEQ ID NO: 4. Therefore, claims to cells and organisms comprising recombinant polynucleotides encoding the polypeptides of the present invention are not anticipated by Caput. For at least these reasons, withdrawal of this ground for rejection is respectfully requested.

B. Hromas is not available as prior art

Regarding the rejection over Hromas, this reference is not available as prior art. In view of the presently pending claims, applicant's priority date goes back to February 1995 and Hromas was published in 1997. Accordingly, applicants respectfully request the lack of novelty rejection over Hromas be withdrawn.

CONCLUSION

Reconsideration of the present application in view of the foregoing amendments and arguments is kindly requested.

It is respectfully urged that the present application is now in condition for allowance. Early notice to that effect is earnestly solicited.

Examiner Switzer is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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